8EHQ-0702-15155

MR 60756

July 29, 2002

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TSCA Document Processing Center
U.S. EPA 7407 M
Ariel Rios Building
EPA East Bldg, Room 6428
1200 Pennsylvania Avenue NW
Washington, DC 20460-0001
Attn: Section 8(e) Submission

Re: TSCA § 8(e) Submission: 8EHQ-0602-15155 Response

Dear Sir or Madame:

On behalf of [ ] is submitting a TSCA § 8(e) submission response for 8EHQ-0602-15155 Response.

This submission asserts confidential business information claims. Accordingly, the substantiation of confidentiality claims was enclosed in the June 11, 2002 submission.

Any questions regarding this submission should be directed to [ ]

Sincerely

COMPANY SANITIZED

( )
[ ]
[ ]

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Enclosures

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[ ]

July 25, 2002

TSCA Document Processing Center
U.S. EPA 7407M
Ariel Rios Bldg.
EPA East Bldg, Room 6428
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001
Attn: Section 8(e) Submission

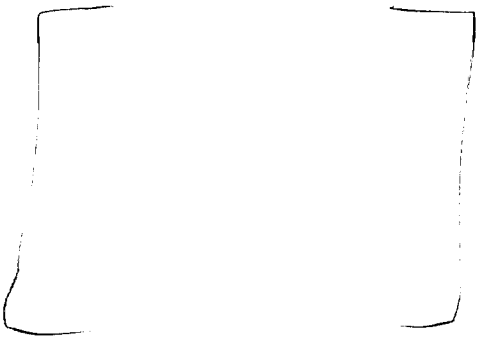
Re: TSCA § 8(e) Submission: 8EHQ-0602-15155 Response

Dear Sir or Madam:

This letter is providing a response to the EPA letter of June 24, 2002 related to the June 11, 2002 [ ] TSCA § 8 submission for a skin sensitization study of [ ] in guinea pigs.

[ ] already had an established standard personal protection policy for employees, which requires that employees wear, as a minimum, protective uniforms, protective gloves, safety glasses, and safety shoes whenever the employee is in the manufacturing area. Currently, [ ] has approximately 20 workers who may be potentially exposed to the tested product. Since obtaining this skin sensitization information, [ ] has begun a training program for its employees (see Attachment 1) regarding the skin sensitization effects of this product, as is mandated by the OSHA Hazard Communication Standard found at 29 CFR § 1910.1200. In addition, [ ] has updated the product MSDS (see Attachment 2) and intends to mail this revised MSDS in the very near future to the approximately 24 customers who have received commercial quantities of this product.

Please note in MSDS Section 11 that this product did not cause any adverse effects in a human skin patch test.



This submission contains confidential business information.

Any questions regarding this submission should be directed to [
].

Attachments

Sincerely,

[ ]
[ ]

Attachment 1

Why Change MSDS ?

The OSHA 1910.1200 regulation states as follows,

1910.1200(g)(5)

"The chemical manufacturer, importer or employer preparing the material safety data sheet shall ensure that the information recorded accurately reflects the scientific evidence used in making the hazard determination. If the chemical manufacturer, importer or employer preparing the material safety data sheet becomes newly aware of any significant information regarding the hazards of a chemical, or ways to protect against the hazards, this new information shall be added to the material safety data sheet within three months. If the chemical is not currently being produced or imported the chemical manufacturer or importer shall add the information to the material safety data sheet before the chemical is introduced into the workplace again."

Why Change MSDS?

The question of significant has to be answered. This is covered by Appendix B of the Hazcom Standard. This following applies.

From 1910.1200 App B

"4. "Adequacy and reporting of data." The results of any studies which are designed and conducted according to established scientific principles, and which report statistically significant conclusions regarding the health effects of a chemical, shall be a sufficient basis for a hazard determination and reported on any material safety data sheet. In vitro studies alone generally do not form the basis for a definitive finding of hazard under the HCS since they have a positive or negative result rather than a statistically significant finding."

This section also allows us to report studies that refute finding of a hazard

"The chemical manufacturer, importer, or employer may also report the results of other scientifically valid studies which tend to refute the findings of hazard."

- Attachment 1 cont'd -

What changes are being made to the MSDS?

MSDS Changes

SECTION 3: HAZARDS IDENTIFICATION

PHYSICAL DESCRIPTION:	Milky-white emulsion
ODOR:	Sweetish odor
POTENTIAL HEALTH EFFECTS:	This product may cause skin, eye, and respiratory irritation. **This product may cause skin sensitization.** Above 200 °C, hydrogen fluoride and other toxic fluorinated compounds may be produced; inhalation of these compounds under these conditions may result in serious lung irritation.

- Attachment 1 cont'd -

MSDS Changes

SECTION 11. TOXICOLOGICAL INFORMATION

ACUTE EFFECTS OF EXPOSURE

Ingestion:	Not Evaluated
Eye Contact:	May cause eye irritation
Skin Contact:	May cause skin sensitization
Inhalation:	May cause respiratory irritation
CHRONIC EFFECTS OF EXPOSURE:	No data available
CARCINOGENICITY:	None of the components in this material is listed by NTP, OSHA or IARC
TOXICOLOGICAL TESTS:	In Vitro Mammalian Chromosome Aberration Test – Negative
	Dermal Irritation (Rabbit) – Negative
	Primary Skin Irritation by Closed Patch (Human) – Negative
	Bacterial Mutation Assay – Negative
	Skin Sensitization by Magnusson & Kligman Method (Guinea Pig) - Positive

OTHER POTENTIAL HAZARDS (OF THE PURE MATERIALS)

Tripropylene glycol:	Oral rat LD50 of 3000 mg/kg

Excessive exposure to thermal degradation products could result in delayed pulmonary edema in some cases, and on very high exposure, damage to the liver and kidneys. These substances may include: perfluoroisobutylene (TLV = 10 ppb), carbonyl fluoride (TLV = 2 ppm TWA, 5 ppm STEL), hydrogen fluoride (TLV = 3 ppm, Ceiling).

MSDS Changes

SECTION 15. REGULATORY INFORMATION

TSCA:	All components registered on TSCA inventory.
EINECS 1987 LIST:	All components are registered on EINECS
CEPA:	Low Volume Exemption
OTHER:	States such as Pennsylvania, New Jersey, California, Vermont, Massachusetts, and Rhode Island may have specific requirements or components of this product listed; consult specific state regulatory requirements for additional information.

[ ] requires labeling with the risk phrase R43 " May cause sensitization by skin contact" in accordance with Commission Directive 93/21/EEC.

Attachment 2

Issued: 6/24/02

MATERIAL SAFETY DATA SHEET

SECTION 1: CHEMICAL PRODUCT & COMPANY IDENTIFICATION

MSDS [ ] ISSUED 06/24/02

SECTION 2: INFORMATION ON INGREDIENTS

COMPONENT	CAS. NO.	Wt%	OSHA (PEL)	ACGIH (TLV)
HAZARDOUS INGREDIENTS				
None				
NON-HAZARDOUS INGREDIENTS				
Water	7732-18-5	64.6	None	None
Fluoroalkyl acrylate copolymer	Trade Secret	30.0	None	None
Emulsifiers	Trade Secret		None	None
Tripropylene Glycol	24800-44-0	5.4	None	None

*All ingredients in quantities ≥ 1% (0.1% for carcinogens) that are potentially hazardous per OSHA definitions.

SECTION 3: HAZARDS IDENTIFICATION

PHYSICAL DESCRIPTION: Milky-white emulsion

ODOR: Sweetish odor

POTENTIAL HEALTH EFFECTS: This product may cause eye, skin, and respiratory irritation. This product may cause skin sensitization. Above 200 °C, hydrogen fluoride and other toxic fluorinated compounds may be produced; inhalation of these compounds under these conditions may result in serious lung irritation.

SECTION 4. FIRST AID PROCEDURES

INGESTION: Consult a physician immediately.

EYE CONTACT: Flush with large amounts of water for 10-15 minutes. Consult a physician if needed.

SKIN CONTACT: Wash affected area with soap and water.

INHALATION: Leave the contaminated area and seek fresh air. If breathing is difficult, contact a physician.

SECTION 5. FIRE FIGHTING MEASURES

FLASH POINT (METHOD USED):	Non-flammable
FLAMMABLE LIMITS:	LEL: None UEL: None
HAZARDOUS COMBUSTION PRODUCTS:	Toxic by-products including Hydrofluoric Acid, Perfluoroisobutylene, and Carbonyl Fluoride may be formed at very high temperatures.
EXTINGUISHING MEDIA:	Alcohol foam, CO_2, dry chemical or water spray
PROTECTIVE EQUIPMENT:	Use NIOSH/MSHA approved SCBA and bunker gear. Evolution of acidic gases may require complete washdown of protective clothing prior to removal.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Ensure cleanup is done only by trained personnel wearing appropriate personal protective equipment. Ventilate area and cover with absorbent material.

Collect spilled material in a container and seal.

Spilled material is a slipping hazard.

SECTION 7. HANDLING & STORAGE

HANDLING

Use only in well ventilated areas.
Safety showers & eyewashes should be available in the work area.
Avoid contact with the skin or eyes.
Do not breath vapor or spray.

STORAGE

Store material at –5 °C (23 °F) to 40 °C (104 °F).
Keep away from heat, steam, and sunlight.
Keep containers tightly closed when not in use.

SECTION 8. EXPOSURE CONTROLS & PERSONAL PROTECTIVE EQUIPMENT

RESPIRATORY PROTECTION:	Use respirator suitable for protection when spraying this material. If material is heated above 200 °C, use a positive pressure air supplied respirator or SCBA.
EYE PROTECTION:	Safety glasses with sideshields or goggles
PROTECTIVE CLOTHING:	Chemical resistant gloves
VENTILATION:	If material is heated above 200 °C, use local exhaust ventilation.
OTHER PROTECTIVE EQUIPMENT:	Eyewash station and safety shower.

SECTION 9. PHYSICAL & CHEMICAL PARAMETERS

BOILING POINT (°C):	Approx. 100°C (Water)
FREEZING POINT (°C):	<-5°C
SPECIFIC GRAVITY (H2O=1):	Approx. 1.10 at 25°C
VAPOR PRESSURE:	No Data
VAPOR DENSITY	No Data
EVAPORATION RATE (Butyl acetate=1):	No Data
SOLUBILITY IN WATER:	Miscible
pH:	3 to 5

SECTION 10. STABILITY & REACTIVITY

STABILITY:	Stable
CONDITIONS TO AVOID:	Excessive heat
HAZARDOUS POLYMERIZATION:	Should not occur
INCOMPATIBILITIES:	May react with metals, such as sodium, magnesium, aluminum at elevated temperatures (above 425 °C); may react upon prolonged exposure to fluorine or in oxygen-fluorine mixtures at high temperatures and pressures. Contact with incompatible materials may result in fire or explosion.
	Hazardous decomposition or by-products and toxic by-products including Hydrofluoric Acid, Perfluoroisobutylene, and Carbonyl Fluoride may be formed at very high temperatures.

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SECTION 12. ECOLOGICAL INFORMATION

BIODEGRADABILITY:	No data
BIOACCUMULATION:	No data

SECTION 13. DISPOSAL CONSIDERATIONS

Comply with Federal, State and Local regulations concerning health and environment when disposing of materials. Regulations may also apply to empty containers, liners, or rinsate. DO NOT INCINERATE unless incinerator is capable of scrubbing hydrogen fluoride and other acidic combustion products.

SECTION 14. TRANSPORT INFORMATION

UN CLASSIFICATION:	Not regulated
DOT HAZARD DESCRIPTION:	Not regulated
CANADIAN TRANSPORTATION OF DANGEROUS GOODS (TDG):	Not regulated

SECTION 15. REGULATORY INFORMATION

TSCA: All components registered on TSCA inventory. Fluoroalkyl acrylate copolymer of [ ] is registered on TSCA Confidential Inventory [ ]

EINECS 1987 LIST: All components are registered on EINECS

OTHER: States such as Pennsylvania, New Jersey, California, Vermont, Massachusetts, and Rhode Island may have specific requirements or components of this product listed; consult specific state regulatory requirements for additional information.

[ ] requires labeling with the risk phrase R43 " May cause sensitization by skin contact" in accordance with Commission Directive 93/21/EEC.

SECTION 16. OTHER INFORMATION

For additional information, refer to the American Conference of Governmental Industrial Hygienists (ACGIG) documentation of TLV's (Threshold Limit Values) for individual components, Fluoropolymers Safe Handling Guide published by The Society of the Plastics Industry, and the DOT Emergency Response Guidebook.

[ ] believes the information in this MSDS to be correct as of the date issued, but [ ] assumes no liability for the accuracy or completeness of the data relied on in preparing this MSDS [ ] makes no warranties in this MSDS, either express or implied, and excludes all warranties, including without limitation any implied warranty of merchantability, fitness for a particular purpose or course of performance, or usage of trade.

[ ] may provide MSDS information in electronic form as a customer service. Due to the remote possibility that electronic transfer may result in errors, omissions or alterations in this information, [ ] makes no representation or warranty as to its completeness or accuracy when so transferred.